K 123922

SIEMENS Healthcare

JAN 16 2013

510(k) Summary

syngo® Dynamics (Version VA10A)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. General Information

Date of Summary Preparation: December 5, 2012

Establishment:

- **Address:** Siemens Medical Solutions USA, Inc.
  400 W. Morgan Road
  Ann Arbor, MI 48108
- **Registration Number:** 1836549
- **Contact Person:** Yuri Ikeda
  Quality Engineer, Quality & Regulatory
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Device Name and Classification:

- **Trade Name:** *syngo*® Dynamics
  Version VA10A
- **Classification Name:** Picture Archiving and Communications System
- **Classification Panel:** Radiology
- **CFR Number:** 21 CFR §892.2050
- **Device Class:** Class II
- **Product Code:** LLZ

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Intended Use:

syngo® Dynamics is an image and information system intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including review, analysis, quantification and reporting.

As a Cardiology PACS and information system, *syngo*® Dynamics supports the physician in interpretation and evaluation of examinations within healthcare institutions, in particular, in Cardiology, Obstetrics and Gynecology or other

departments.

syngo® Dynamics is not intended to be used for displaying of digital mammography images for diagnosis in the U.S.

Device Description:

This premarket notification addresses the Siemens *syngo*® Dynamics Version VA10A Picture Archiving and Communication System.

The system is a "software only" medical device. It defines recommended requirements to the hardware it runs on. The hardware itself is not considered a medical device and not in the scope of this 510(k) submission.

syngo® Dynamics is a system that includes a DICOM Server which receives, stores, distributes, and archives images from digital image acquisition devices such as ultrasound, computer tomography, magnetic resonance and x-ray angiography machines. The system has workplaces that can be used to review, edit, and manipulate image data, as well as to generate quantitative data, qualitative data, and diagnostic reports.

syngo® Dynamics supports the physician in diagnosis and treatment planning. It also supports storage and archiving of DICOM Structured Reports. In a comprehensive imaging suite *syngo*® Dynamics integrates Hospital / Radiology / Cardiology Information Systems (HIS/RIS/CIS) to enable customer specific workflows.

syngo® Dynamics Version VA10A provides advanced reporting support for cardiology, OB/GYN, MFM (maternal fetal medicine), vascular ultrasound, including specific echo and cath lab oriented features for documentation support in the cardiology department.

Data Management:

syngo® Dynamics allows all authorized personnel fast and continuous access to data such as cardiovascular images and information. Its functionality ranges from availability of images with regard to data security, open interfaces, storage media and central system administration, to provide a flexible storage hierarchy.

Technological Characteristics:

syngo® Dynamics is a "software only" system, which will be delivered on CD-ROM / DVD to be installed on common IT hardware. Hardware must meet the defined requirements. Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by special trained service technicians.

The backend communication and storage solution is based on Windows 2008 operating system. The client machines are based on Windows XP, and Windows 7. Any hardware platform, which meets the specified recommended hardware and software requirements and with successful installation verification and

validation activities can be supported. *syngo*® Dynamics supports DICOM formatted images and objects.

syngo® Dynamics Version VA10A will be used to display, process, read, report, communicate, distribute and store digital medical images, much like its predicate, *syngo*® Dynamics Version 9.0 (K102150).

The difference between the *syngo*® Dynamics Version VA10A and the predicate device *syngo*® Dynamics Version 9.0 are to give the subject device greater capabilities than the predicate device. *syngo*® Dynamics Version VA10A has similar technological characteristics as the predicate device and is similar to the functionalities of the predicate device. The table below summarizes the similarities and the differences between the two devices.

Functionality	***syngo*® Dynamics Version VA10A**	***syngo*® Dynamics Version 9.0**
Manufacturer	Siemens Medical Solutions USA, Inc.	Siemens Medical Solutions USA, Inc.
Intended Use	*syngo*® Dynamics is an image and information system intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including review, analysis, quantification and reporting. As a Cardiology PACS and information system, syngo® Dynamics supports the physician in interpretation and evaluation of examinations within healthcare institutions, in particular, in Cardiology, Obstetrics and Gynecology or other departments. *syngo* Dynamics® is not intended to be used for displaying of digital mammography images for diagnosis in the U.S.	*syngo*® Dynamics is a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation. *syngo*® Dynamics is not intended to be used for reading of mammography images.

Functionality	*syngo*® Dynamics Version VA10A	*syngo*® Dynamics Version 9.0
Operating Systems	**Server** Windows 2008 R2 Server Standard Edition R2 SP1 or SP2 (64-bit) **Workplace** Microsoft Windows XP SP2 or higher • 32-bit or 64-bit, or Microsoft Windows 7 or Windows 7 SP1 or higher • 32-bit or 64-bit • Ultimate, Professional, Enterprise, Ultimate N, Professional N, or Enterprise N **Portal Website Host** Windows Server 2008 R1 32-bit or greater	**Server** Windows Server 2008 R2 SP1 Standard Edition (64-bit) **Workplace** Windows 2000, 2003, XP, Vista, 7 (32 or 64-bit) **Portal Website Host** Windows Server 2008 R1 32-bit or greater
Image Source	DICOM Ultrasound, XA, CT, MR, DX, DR and Nuclear Medicine, including PET.	DICOM Ultrasound, XA, CT, MR, DX, DR and Nuclear Medicine, including PET.
Image Display	Ultrasound, XA, CT, MR, DX, DR, PET and Nuclear Medicine through Corridor4DM	Ultrasound, XA, CT, MR, DX, DR, PET and Nuclear Medicine through MI Mobile or Corridor4DM
Data Export	DICOM, bmp, avi	DICOM, bmp, avi
Image Communication	Within the network, the following communication protocols are used: • TCP/IP: for communication and transport • DICOM and HL7 at application level • HTTP for communication and transport of thumbnails	Within the network, the following communication protocols are used: • TCP/IP: for communication and transport • DICOM and HL7 at application level • HTTP for communication and transport of thumbnails
Image Data Compression	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate.	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate.
Imaging Algorithms	Window/Leveling, Edge Enhancement, and Digital Subtraction	Window/Leveling, Edge Enhancement, and Digital Subtraction
Quantitative Algorithms	Pixel Size Evaluation	Pixel Size Evaluation
Network Access	Yes	Yes
Analysis	Yes	Yes
Reporting	Yes	Yes
Multimodality storage and review	Yes	Yes

Functionality	*syngo*® Dynamics Version VA10A	*syngo*® Dynamics Version 9.0
Web Server for images and clips	Yes	Yes
Report upload to Information Systems	Yes, through broker or interface engine	Yes, through broker or interface engine
DICOM Structured Reporting	Yes	Yes
Export/Import Data Sets via removable media or network means	Yes	Yes
Vascular Quantification	Yes, measurements and calculations	Yes, measurements and calculations
Data Mining	Yes	Yes
Discrete Data Export	Yes	Yes
Cardiac Measurements	Yes	Yes
Interactive graphical documentation for reporting	Yes, through Soarian Cardiology, version 2.0 utilizing patient/user context sharing	Yes, through Soarian Cardiology, version 2.0 utilizing patient/user context sharing
Hemodynamic data import (third party vendor)	Yes	Yes
Web Reporting	Yes	Yes
Hardware	Software-only option for server Workstation: software only (HW is not part of the medical device, but needs to meet recommended requirements as specified by *syngo* Dynamics)	Software-only option for server Workstation: software only (HW is not part of the medical device, but needs to meet recommended requirements as specified by *syngo* Dynamics)
Collaborative Reporting	Yes	No
Mobile Device Support	Yes – Non-diagnostic, and read-only. Support Apple iPhone and iPad.	No

Summary of Non-Clinical Tests:

Integration and System Testing were performed for verification and validation of the device. Siemens Medical Solutions USA, Inc. complies with voluntary standards DICOM Version 3.x (2011), IEC/ISO 10918-1:1994 + TC 1:2005 (JPEG), ISO 14971:2007, IEC 62304:2006, HL7 Version 2.3.1, IEC 62366:2007, and SMPTE.

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify potential hazards. These potential hazards are controlled via software development, labeling, and verification and validation testing.

The device has no patient contacting materials and is used only by trained professionals. The output of the device is evaluated by trained professionals allowing sufficient review for identification and intervention in the event of a malfunction.

Siemens believes that *syngo*® Dynamics Version VA10A is as safe and effective as its predicate device as it does not, raise new types of safety and effectiveness concerns, or introduce new technology.

Substantial Equivalence

The *syngo*® Dynamics Version VA10A, addressed in this premarket modification is substantially equivalent to the following commercially available device:

Manufacturer	*Predicate Device Name*	*FDA Clearance Number*
Siemens Medical Solutions USA, Inc.	*syngo* Dynamics Version 9.0	K102150

The potential hazards of modifications to the device have been evaluated and controlled as part of the product development process, including risk analysis and design considerations. Siemens conducts testing to verify the design output met the design input requirements and to validate the device conformance to the intended use. Predefined acceptance criteria was met and demonstrated that the device is as safe and effective as the predicate device.

In summary, Siemens is of the opinion that *syngo*® Dynamics Version VA10A does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 16, 2013

Siemens Medical Solutions USA, Inc.
% Mr. Yuri Ikeda
Quality Engineer, Quality & Regulatory
TUV SUD America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K123922
Trade/Device Name: syngo Dynamics (Version VA10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 17, 2012
Received: December 20, 2012

Dear Mr. Ikeda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123922

Device Name: syngo® Dynamics (Version VA10A)

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123922